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Attorney Docket No. 17882-705

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)	PATENT APPLICATION
)	
Richard Wisniewski et al.)	Group Art Unit: 3743
)	
Application No.: 08/895,782)	Examiner: Ford
)	
Filed: July 17, 1997)	
)	
Title: FREEZING AND THAWING)	
VESEL WITH THERMAL BRIDGE)	
FORMED BETWEEN CONTAINER)	
<u>AND HEAT EXCHANGER</u>)	DATE: October 8, 1999

DECLARATION UNDER 37 C.F.R. § 1.132

I, V. Bryan Lawlis, Jr., declare as follows:

1. I received a Ph.D. in Biochemistry from Washington State University in 1979. I am currently the Chairman of Covance Biotechnology Services, Inc.

2. Prior to my current position, I was President and Chief Executive Officer of Covance Biotechnology Services, Inc. I have 18 years experience in the biotechnology and biopharmaceutical industry where I have served in a variety of scientific and management positions brining a diverse array of biotechnology and biopharmaceutical products to market.

3. I am not a paid consultant, employee, or agent of the assignee of this patent application. I am not receiving compensation in exchange for providing this testimony.

5. I have read and understood U.S. Patent Nos. 5,609,035 to Cothorn et al. ("Cothorn"); 5,524,706 to Nakamura et al. ("Nakamura"); and 1,874,578 to Morrison ("Morrison").

6. I understand that, during the prosecution of the present invention, an issue has arisen regarding the definition of the term "biopharmaceutical product."

7. It is my opinion that an accurate and clear definition of biopharmaceutical product is: **a product derived from biological sources that has an intended therapeutic application and whose manufacturing is or will be regulated by pharmaceutical or veterinary regulatory agencies.**

8. It is my opinion that the Cothorn, Nakamura, and Morrison references do not suggest nor teach biopharmaceutical products, or devices or methods useful in processing biopharmaceutical products. In particular, it is my opinion that conventional milk, as disclosed in the Morrison reference, or conventional orange juice, as disclosed in the Cothorn reference, are not biopharmaceutical products.

9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

By: V. Bryan Lawlis, Jr.
V. Bryan Lawlis, Jr.

Date: October 7th, 1999
October 6, 1999

Country of Citizenship: U.S.A.

Residence: 400 Swan's Mill Crossing
Raleigh, NC 27614

Post Office Address: Same as above